UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,934	03/08/2002	Paul Averback	018792-0199	7362

22428 7590 06/23/2005

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,934	AVERBACK, PAUL	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed May 26, 2004 is acknowledged and has been entered.

2. Claims 1-46 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 4 and 26, drawn to a method for treating a condition in a patient, wherein said condition is a benign tumor, classified in class 514, subclass 2.

Group II. Claims 4 and 26, drawn to a method for treating a condition in a patient, wherein said condition is a malignant tumor, classified in class 514, subclass 2.

Group III. Claims 5-7 and 27-29, drawn to a method for treating a condition in a patient, wherein said condition is a hyperplasia, hypertrophy, or overgrowth of a tissue, classified in class 514, subclass 2.

Group IV. Claims 8 and 30, drawn to a method for treating a condition in a patient, wherein said condition is a virally altered tissue, classified in class 514, subclass 2.

Group V. Claims 8 and 30, drawn to a method for treating a condition in a patient, wherein said condition is a bacterially altered tissue, classified in class 514, subclass 2.

Group VI. Claims 8 and 30, drawn to a method for treating a condition in a patient, wherein said condition is a parasitically altered tissue, classified in class 514, subclass 2.

Group VII. Claims 9 and 31, drawn to a method for treating a condition in a patient, wherein said condition is a malformation of a tissue, classified in class 514, subclass 2.

Group VIII. Claims 10, 11, 32, and 33, drawn to a method for treating a condition in a patient, wherein said condition is a cosmetic modification to a tissue, classified in class 514, subclass 2.

Group IX. Claims 12, 15, 34, and 37, drawn to a method for treating a condition in a patient, wherein said condition is a vascular disease, classified in class 514, subclass 2.

Group X. Claims 13 and 35, drawn to a method for treating a condition in a patient, wherein said condition is hemorrhoids, classified in class 514, subclass 2.

Group XI. Claims 14 and 36, drawn to a method for treating a condition in a patient, wherein said condition is varicose veins, classified in class 514, subclass 2.

Group XII. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is an inflammatory disease, classified in class 514, subclass 2.

Group XIII. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is an autoimmune disease, classified in class 514, subclass 2.

Group XIV. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is a metabolic disease, classified in class 514, subclass 2.

Group XV. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is a hereditary/genetic disease, classified in class 514, subclass 2.

Group XVI. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is a traumatic disease, classified in class 514, subclass 2.

Group XVII. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is a physical injury, classified in class 514, subclass 2.

Group XVIII. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is an nutritional deficiency disease, classified in class 514, subclass 2.

Group XIX. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is an infectious disease, classified in class 514, subclass 2.

Group XX. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is an amyloid disease, classified in class 514, subclass 2.

Group XXI. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is a fibrotic disease, classified in class 514, subclass 2.

Group XXII. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is an storage disease, classified in class 514, subclass 2.

Group XXIII. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is a congenital malformation, classified in class 514, subclass 2.

Group XXIV. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is enzyme deficiency disease, classified in class 514, subclass 2.

Group XXV. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is poisoning, classified in class 514, subclass 2.

Group XXVI. Claims 16 and 38 drawn to a method for treating a condition in a patient, wherein said condition is intoxication, classified in class 514, subclass 2.

Group XXVII. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is an environmental disease, classified in class 514, subclass 2.

Group XXVIII. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is a radiation disease, classified in class 514, subclass 2.

Group XXIX. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is an endocrine disease, classified in class 514, subclass 2.

Group XXX. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is a degenerative disease, classified in class 514, subclass 2.

Group XXXI. Claims 16 and 38, drawn to a method for treating a condition in a patient, wherein said condition is a mechanical disease, classified in class 514, subclass 2.

Group XXXII. Claim 46, drawn to a method for treating a condition in a patient, classified in class 514, subclass 44.

4. Claims 1-3, 17-25, and 39-45 are linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or

divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-X are patentably distinct, each from the other, as each is a process for treating a pathologically and/or etiologically distinct condition. Accordingly, each of the inventions has a different objective and comprises different process steps, as, for example, each comprises administering a polypeptide to a member of a different population of patients afflicted by a different condition. Inasmuch as the conditions treated using the claimed processes are different, each invention has a different criteria for success, as, for example, each necessarily measures a different endpoint.

The inventions in Groups I-XXXI and the inventions in Group XXXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation and different effects, as the inventions of Groups I-XXXI are processes comprising administering a polypeptide to a mammal, whereas the inventions of Group XXXII are processes comprising administering a polynucleotide to a mammal. Polypeptides and polynucleotides are chemically distinct products, since polypeptides are composed of polymers of amino acids, whereas polynucleotides are composed of polymers of nucleotides. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, a polypeptide can be produced by means, other than the recombinant means by which a polynucleotide encoding a polypeptide might

be used to produce the polypeptide, since a polypeptide can be produced (or isolated) by biochemical means, including, for example, affinity chromatography. In addition, while the polynucleotide might encode the polypeptide, generally, it can also encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a polynucleotide can be used as a probe in hybridization-based analyses, the information provided by a polynucleotide can be used isolate different polynucleotides encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed polynucleotide. Consequently, the disclosed relationship between a polynucleotide capable of encoding a polypeptide and the polypeptide is not exclusive, since either the claimed polynucleotide or the claimed polypeptide can also be related to other polynucleotides or polypeptides, which are materially and chemically different from the claimed inventions. Moreover, as a consequence of the different modes of action in administering a pharmaceutical comprising either a polypeptide or a polynucleotide, the inventions of Groups I-XXXI and the inventions of Group XXXII have acquired a separate status in the art, as evidenced by their different classifications.

6. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to patentably distinct species of the claimed invention, wherein said NTP is selected from the group consisting of (a) SEQ ID NO: 1, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, or an enantiomer thereof, (b) SEQ ID NO: 2, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, and

an enantiomer thereof, (c) SEQ ID NO: 3, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, and an enantiomer thereof, (d) SEQ ID NO: 4, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, and an enantiomer thereof, (e) SEQ ID NO: 5, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, and an enantiomer thereof, (f) SEQ ID NO: 6, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, and an enantiomer thereof, (g) SEQ ID NO: 7, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, and an enantiomer thereof, (h) SEQ ID NO: 8, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, and an enantiomer thereof, (i) SEQ ID NO: 9, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, and an enantiomer thereof, (j) neural pancreatic tread protein, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, and an enantiomer thereof, and (k) pancreatic thread protein, a fragment thereof, a homolog thereof, a variant thereof, a derivative thereof, a peptide mimetic thereof, a reverse D-peptide derivative thereof, and an enantiomer thereof.

Each species of invention comprising administering a species of NTP is distinct from the others comprising administering a different species of NTP, since each species of NTP is a distinct NTP having an amino acid sequence that differs from the others and/or which is derived from a distinct source. Accordingly, the examination of each species of invention comprising administering any one species of NTP would require a unique search that is not required for examination of any of the other species of invention comprising administering a different species of NTP, because the search of any one species of NTP will not provide adequate information regarding any other, and

therefore the search of any one species of invention will not provide adequate information regarding a different species of invention. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the species of NTP to which the claims are directed, which species of invention will be considered for prosecution on the merits and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that a step of administering one novel and nonobvious species of NTP would render the species of invention allowable over the prior art (but not necessarily over 35 U.S.C. §§ 101 and 112).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
June 22, 2005